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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,445	11/01/2000	Jesus Prieto Valtuena	U013039-2	8974

140 7590 08/24/2004

LADAS & PARRY
26 WEST 61ST STREET
NEW YORK, NY 10023

EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/674,445

Applicant(s)

PRIETO VALTUENA ET AL.

Examiner

Jegatheesan Seharaseyon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 16-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 16-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This office action is in response to the remarks filed on 5/11/2004. Claims 11-13 and 16-22 are pending.
2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.
3. The declaration provided by Dr. Jesus Prieto Valtuena under 37 CFR 1.132 filed 5/24/2004 has been fully considered.

Claim Rejections - 35 USC § 103, maintained

4. The rejection of claims 11-13 and 16-22 under 35 USC 103 (a) as being unpatentable over unpatentable over Foster et al. (U.S. Patent No: 6,007,805) in view of Albrecht (6, 172,046) is maintained for the reasons set forth in the previous Office Action mailed on the 25th of February 2004 pages 4 and 5. Applicant's arguments filed on 5/11/2004 have been fully considered but are deemed to be not persuasive.

Applicant argues that Foster et al. does not teach HCV causing liver disease. Further, Applicant asserts that the reference does not teach the use of IFN- α in patients with having chronic hepatitis C infection. It is also asserted that Albrecht does not show or suggest that claimed subtype, IFN- α 5, would be suitable for treating HCV. However, Foster et al. reference does teach that IFN- α 5 along with IFN- α 2 and IFN- α 8 are very potent antivirals based on an assay where, HuH7 (liver cells) are challenged by hepatitis A virus (column 3, lines 20-25). In addition, contrary to Applicant's argument that assays are performed with EMC virus assays were also performed with hepatitis A virus using liver cells.

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Applicant also asserts that the Foster et al. reference teaches the use of IFN α -8 and not the use IFN α -5. Foster et al. recites IFN α -8 to be the preferred embodiment. However, it also extensively discusses the use of IFN α -5 as an antiviral agent in liver cells (column 2, lines 16-20).

Further, Albrecht teaches that chronic infection with hepatitis C virus can cause hepatitis C eventually resulting in cirrhosis of the liver, decompensated liver disease and /or hepatocellular carcinoma (column, 1 lines 6-12). The reference also teaches the use of IFN α in patients having chronic hepatitis C infection to eradicate HCV (column 1, lines 50-53). Therefore, Albrecht provides the motivation to treat patients with chronic HCV infection with IFN α proteins and the potent antiviral effect of IFN α -5 in liver cells disclosed by Foster et al., with a reasonable expectation of success. It should be noted that, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant is also by providing a declaration is attempting to show that using IFN α -5 in liver cells to treat HCV provides unexpected and surprising results (cell signaling and more efficient induction of antiviral genes). This is not found to be persuasive because Foster et al. have previously used of both IFN α -2 and IFN α -5 in liver cells and demonstrated their potent antiviral activity. In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal

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evidence of nonobviousness fails to outweigh the evidence of obviousness.

Therefore, The rejection of claims 11-13 and 16-22 and 23-27 under 35 USC 103

(a) as being unpatentable over unpatentable over Foster et al. (U.S. Patent No:

6,007,805) in view of Albrecht (6, 172,046) is maintained.

5. No claims are allowable.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The

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fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JS 08/04


BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600